UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,653	04/20/2004	C. Randal Mills	15672US01	4918

23446 7590 02/23/2007

MCANDREWS HELD & MALLOY, LTD
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER	
YOO, REGINA M	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,653	MILLS ET AL.	
	Examiner	Art Unit	
	Regina Yoo	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *14-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/22/04,10/21/05,3/03/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-13, drawn to a process for making an implant more suitable for implantation, classified in class 422, subclass 28.

   II. Claims 14-26, drawn to a process for making an implant more suitable for implantation, classified in class 422, subclass 28.

   III. Claims 27-42 and 63-64, drawn to a process for making an implant more suitable for implantation, classified in class 422, subclass 28.

   IV. Claims 43-60, drawn to an apparatus for applying tension to an implant, classified in class 254, subclass 199.

   V. Claims 61-62, drawn to an apparatus for packaging an implant, classified in class 53, subclass 235.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, as well as I and III, are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination of Group II as claimed because Invention I does not claim the particular specific of contacting the implant with a

peroxide for a specific time period ("for less than 80 consecutive minutes") as the Invention II claims. In addition, Invention I does not require application of tension to the soft tissue while contacting the tissue with a cleaning agent as the Invention III does. The subcombinations of Inventions II and III have utility by themselves as a sterilizing process on their own.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions I-III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of Groups I, II and III as claimed can be practiced by another and materially different apparatus than the one in Group IV, where the fasteners are attached to a substrate at a given distance at least somewhat longer than

the implant to apply tension instead of having a resilient member disposed between the two fasteners. In addition, the apparatus of Group IV as claimed can be used to practice another and materially different process than that of Group I, where the implant is not treated with fluid agents but rather with gaseous agents.

4. Inventions I-III and V are directed to related process and apparatus. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different function and effect. The function of the inventions in Groups I-III is to sterilize and treat an implant suitable for a recipient whereas the function of the invention in Group V is to package a product resulting from the process of Groups I-III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions IV and V are directed to related apparatus. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the

invention as claimed in Groups IV and V have a materially different design and mode of operation where the apparatus of Group IV is designed with fasteners and a resilient member between the fasteners to apply tension to an implant whereas the design of the apparatus of Group V would encompass features such as packaging material feeder, conveyor system, sealing mechanism, etc. to package sterilized implant materials. Thus, the mode of operation of the apparatus in Group IV and Group V will be materially different. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

7. If Group III is chosen, this application contains claims directed to the following patentably distinct species:

- Specie A drawn to a process where the cleaning agent is an oxidizing sterilant;
- Specie B drawn to a process where the cleaning agent comprises a disinfectant;
- Specie C drawn to a process where the cleaning agent is a decontaminating agent;

- Specie D drawn to a process where the cleaning agent comprises a detergent.

The species are independent or distinct because each of the cleaning agents is of different composition.

8. During a telephone conversation with Michael Harlin on January 30, 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant's election with traverse of Group I during the telephone conversation on January 30, 2007 is acknowledged. The traversal is on the ground(s) that there would not be an undue burden on the examiner. This is not found persuasive because the Groups I-III and Group IV and Group V acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. In regards to the Groups I, II and III, the inventions require a different field of search and restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

10. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills (WO 00/29037).

As to Claim 1, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant at least partially comprises a soft tissue (page 12, line 23), the process comprising:

(a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols (page 18, Table I Step 2 with fluid E);

(b) contacting the implant with an oxidizing sterilant (page 18, Table I Step 3 with fluid C); and

(c) contacting the implant with a rinsing fluid (page 18, Table I Step 4; page 19, lines 9-12).

As to Claim 2, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12).

As to Claim 3, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising:

d) contacting the implant with an oxidizing sterilant (page 19, lines 20-24; Table II); and

(e) contacting the implant with a rinsing fluid (page 20, Table II Step 4', or page 21, lines 1-3).

As to Claim 4, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the

contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12, or page 20, Table II Step 4' and page 21, lines 1-3).

As to Claim 5, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c) (page 18, Table I Step 4).

As to Claim 7, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid is selected from the group consisting of alcohols, acetone, water, and mixtures thereof (page 18, Table I Step 4 with fluid E or mixtures; page 20, Table II Step 4' with fluid J or mixtures; page 19, lines 10-11; page 21, lines 1-2).

As to Claim 8, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms (page 18, Table I Step 4 with fluid E where the alcohol is "ethanol or isopropanol" or page 20, Table II Step 4' where the fluid is J – in the form of "isopropanol, methanol").

As to Claim 9, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein step (b) comprises

contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10% (page 18, Table I Step 3 with fluid C where the concentration is 3% or page 20, Table II with fluid I where the concentration is 6%).

As to Claim 10, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises at least one tendon or ligament (page 32, line 5).

As to Claim 11, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises a tendon having bone attached thereto (page 31, lines 21-31).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037).

Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein prior to step (b) (for example during step (a)) alcohol is contacted with the implant (page 18, Table I Step 2 with fluid E). While Mills ('037) does not specifically teach that the implant contains an amount of the alcohol in the implant, it would have been obvious to one of ordinary skill in this art that the alcohol remains in the implant after the treatment as Mills does not disclose that the alcohol is removed to waste before carrying out step (b); only fluid removal step mentioned by Mills is "after step 4 in Table I, the cleaning fluid is removed to waste under positive pressure" (page 19, line 9).

Thus, Claim 6 would have been obvious within the meaning of 35 U.S.C. 103(a) within teachings of Mills ('037).

16. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Cook (6206931).

Mills ('037) is relied upon for disclosure described in the rejection of claims 1-5 under 35 U.S.C. 102(b) and under 35 U.S.C. 103(a) for claim 6.

Mills ('037) fails to teach that the sterilizing process for treating an implant is further comprised of applying tension to the soft tissue at least during part of step (b) or during each of steps (a)-(c).

Cook ('931) discloses that a tissue source for an implant is sterilized to yield a collagen-based matrix (Abstract) that can be "employed to prepare tissue graft constructs useful in orthopedic soft tissue applications, for example in tendon or ligament repair" (Col. 11, lines 54-56) and further discloses that "for tendon and ligament replacement applications, ...[the implant tissue] can be conditioned by the prolonged application of a load on the longitudinal axis of the segment (e.g. by suspending a weight from the segment) ... [or] can be preconditioned by stretching in the lateral dimension" (Col. 11, lines 62-67 and Col. 12, lines 1-3).

While Cook ('931) appears to disclose that the tensioning step occurs after the disinfection steps, it would have been obvious to one of ordinary skill in this art at the time of invention to provide the tensioning step either before, during or after the disinfection process of a soft tissue such as a tendon or a ligament in order to obtain a properly conditioned/tensioned connective tissue graft to implant in a patient as it was well known in the art at the time of invention to tension a graft before the actual implantation in order to (1) decrease its elongation once implanted and (2) tensioning of the graft after the graft is partially in place is awkward to perform. Furthermore, tensioning of the implanted tissue prior to implantation also (3) allows a full range of motion for a patient after receiving the implant which is the reason why the "grafts used

in orthopedic applications are typically placed under tension in their surgical installation" ('931, Col. 12, lines 43-44).

Thus, Claims 12-13 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037) and Cook ('931).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina Yoo whose telephone number is 571-272-6690. The examiner can normally be reached on Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Piazza Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GLADYS P. CORCORAN
SUPERVISORY PATENT EXAMINER

RY